In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: March 31, 2021

C.C.,	*	No. 17-708V
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Decision; Entitlement; Ruling on the Record; Hepatitis B Vaccine; Shoulder Injury Related to Vaccine Administration ("SIRVA")
Respondent.	*	

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.
Sarah C. Duncan, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

On May 30, 2017, C.C. ("Petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program").[2] ECF No. 1. Petitioner alleged that the Hepatitis B vaccine she received on March 23, 2016, caused her to sustain a shoulder injury related to vaccine administration ("SIRVA"). *Id.* at 1. Petitioner later amended her petition to also allege that the vaccination "caused in fact" her injury. Am. Pet. at 1, ECF No. 46. For the reasons discussed herein, I deny Petitioner's claim and find that Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed her petition on May 30, 2017. ECF No. 1. The case was assigned to then-Chief Special Master Dorsey the next day. ECF No. 4. On June 7, 2017, Petitioner filed several exhibits, including her declaration, vaccination record, and medical records from several

[1] This Decision shall be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet**. In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted Decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

physicians and healthcare providers, as well as a statement of completion. ECF Nos. 7–8. After a status conference on July 24, 2017, the presiding special master ordered Respondent to submit a status report indicating how he wished to proceed. Scheduling Order, docketed July 11, 2017; Min. Entry, docketed July 28, 2017; ECF No. 10. In said status report, Respondent declined to consider settlement and requested until March 30, 2018, to file a Rule 4(c) report. ECF No. 15.

In his Rule 4(c) report, filed on March 30, 2018, Respondent requested that the presiding special master dismiss Petitioner's petition, arguing that "there is not preponderant evidence demonstrating the requisite facts to establish compensation for [P]etitioner's alleged SIRVA." Resp't's Report at 6, ECF No. 19. Respondent stated that "[P]etitioner's contemporaneous medical records demonstrate that the onset of her SIRVA was at least two months post-vaccination[,]" rather than within forty-eight hours as required by the Vaccine Injury Table. *Id.* at 5–6 (citing 42 C.F.R. § 100.3(a)(VIII)(B)). Respondent noted that Petitioner had at least "four medical assessments between her immunization . . . and when she first reported right shoulder pain[.]" *Id.* at 6. He stated that "[t]his time period is outside of a medically appropriate interval to ascribe causation to the vaccine." *Id.* Respondent further argued that "[o]nly [P]etitioner – as opposed to any of her numerous medical providers – raised the possibility that her shoulder injury was due to the [H]epatitis B vaccination." *Id.* He also stated that her "shoulder pain could have been related to a motor vehicle accident" Petitioner was in the same month as her vaccination. *Id.* Additionally, Respondent asked that Petitioner provide records from the physician who prescribed her Risperidone, an antipsychotic medication, and from her treatment following her motor vehicle accident ("MVA"). *Id.* at 3, 3 n.2, 4 n.3.

Accordingly, the presiding special master ordered Petitioner to submit records pertaining to her MVA. In response, on June 20, 2018, Petitioner filed declarations from her daughters and her chiropractic records, which she updated a week later. *See* ECF Nos. 21, 23. Additionally, Petitioner submitted a declaration regarding her MVA on July 3, 2018. *See* ECF No. 24.

In response to motions from Petitioner, the presiding special master granted Petitioner permission to serve medical providers with subpoenas to obtain further medical records on July 27, 2018. *See* ECF Nos. 25–28. The presiding special master also order Petitioner to produce the records pertaining to her antipsychotic medication Respondent previously requested. ECF No. 29 at 1. Additionally, the presiding special master directed Petitioner to indicate whether Petitioner intended to proceed with her case. *Id.* at 2. Petitioner filed some medical records by August 27, 2018, as well as a statement of completion pertaining to those records. *See* ECF Nos. 30, 32. Petitioner, however, also filed a status report stating that one of the medical offices she had served with a subpoena had closed and that she had not received a response to the subpoena. ECF No. 31. Petitioner stated that she wanted to continue with her case and requested a status conference. *Id.*

The presiding special master held a status conference with the parties on September 25, 2018. Min. Entry, docketed Sept. 25, 2018; Scheduling Order at 1, ECF No. 34. During the status conference, the parties discussed the weaknesses in Petitioner's case, as well as discrepancies regarding when the MVA occurred. ECF No. 34 at 1–2. Petitioner requested time to obtain additional evidence and "discuss a litigative risk settlement with [R]espondent . . . ." *Id.* at 2. Respondent indicated that he was willing to review a demand if Petitioner were to submit one. *Id.* Petitioner submitted a demand to Respondent on October 19, 2018. *Id.*; ECF No. 33. The presiding special master ordered Petitioner to provide additional evidence to address problems noted in

Respondent's Rule 4(c) report and a status report regarding a potential litigative risk settlement by December 3, 2018. ECF No. 34 at 2.

In response, Petitioner stated in a status report that she was unable to file an accident report because no such report existed. ECF No. 36 at 1. Petitioner addressed issues with her case but stated that "[t]here is sufficient medical documentation showing her right shoulder pain was more likely than not caused by the Hepatitis B vaccine." *Id.* at 2–3. Petitioner affirmed that she wished to continue her case. *Id.* at 3. The presiding special master ordered Respondent to submit a status report stating his current position and response to Petitioner's demand. Scheduling Order, docketed Dec. 12, 2018. Following multiple delays, Respondent stated that "he [was] not in a position to pursue informal resolution at [that] time" and requested a status conference. ECF No. 40 at 1.

This case was reassigned to the undersigned on May 22, 2019. *See* ECF Nos. 41–42. I held a status conference with the parties on August 6, 2019. Min. Entry, docketed Aug. 6, 2019; Scheduling Order, ECF No. 43. During the status conference, I, citing Petitioner's pre-existing medical history, raised concerns regarding Petitioner's credibility and the general lack of evidence in the medical record that corroborated an onset of SIRVA-related shoulder pain close-in-time to Petitioner's vaccination. ECF No. 43. I encouraged Petitioner to submit additional probative evidence, such as pharmacy records or witness statements. *Id.* Petitioner requested that this case be decided via a ruling on the record. *Id.* I directed Petitioner to submit any additional corroborative evidence she wished to be considered by September 5, 2019. *Id.*

On September 4, 2019, Petitioner filed a motion for an extension of time to submit corroborative evidence and a motion to amend her petition to include causation-in-fact. ECF Nos. 44–45. I granted both motions. Scheduling Order, docketed Sept. 5, 2019; Scheduling Order, docketed Sept. 6, 2019. Pursuant to my orders, Petitioner filed her amended petition on September 10, 2019, as well as pharmacy records and witness declarations on October 3, 2019. ECF Nos. 46–47.

After receiving Petitioner's evidence, I directed the parties to file simultaneous briefs in support of their positions. Scheduling Order, docketed Oct. 7, 2019. On December 23, 2019, the parties submitted their simultaneous briefs in support of a ruling on the record. ECF Nos. 49–50.

I have determined that a ruling on the record is appropriate in this case. Because Petitioner is an adult and her injury is not life-threatening or severely debilitating, Petitioner would not be eligible for a hearing until at least late 2022. Petitioner requested a quicker determination, specifically in the form of a ruling on the record. Expert testimony is not necessary in this case because SIRVA is commonly seen in the Program. Furthermore, Petitioner's testimony would not have helped her case because the record, to the extent that it is inconsistent with her declarations, is more compelling.

This matter is now ripe for consideration.

II. Evidence

A. Relevant Medical History

Petitioner was born on March 21, 1968. *E.g.*, Pet'r's Ex. 3 at 1, ECF No. 7-3. Her medical history prior to vaccination is notable for hypertension, hyperlipidemia, gastroesophageal reflux

disease, obesity, smoking, and schizoaffective disorder.[3] *See e.g.*, Pet'r's Ex. 16 at 1–54, ECF No. 30-1; Pet'r's Ex. 10 at 1–5, ECF No. 7-10. Her medical records also include notations of depression, anxiety, hypoglycemia, edema, schizophrenia, allergic rhinitis, an unspecified hormone disorder, panic attacks, panic disorder, being edentulous, tingling of fingertips, leg pain, back pain, and chronic pain. Pet'r's Ex. 3 at 3–6; Pet'r's Ex. 6 at 2, ECF No. 7-6; Pet'r's Ex. 10 at 18–21, 23–24, 33–34, 86; Pet'r's Ex. 18 at 15, ECF No. 35-2; Pet'r's Ex. 16 at 23, 33. Records from her former psychiatrist also indicate that Petitioner may have been pursuing legal action against him for prescribing the wrong dosage of a medication. *See* Pet'r's Ex. 16 at 64.

Petitioner received the first dose of the Hepatitis B vaccine on March 23, 2016, at HB Medical & Wellness Care. Pet'r's Ex. 3 at 1–2. The vaccination record does not mention the administration site of the vaccine. *See* Pet'r's Ex. 2 at 1–2, ECF No. 7-2.

On March 28, 2016, five days post vaccination, Petitioner presented to Patient First – Waldorf complaining of "[i]ntermittent abdominal cramping, diarrhea, vomiting . . . over the past 2-3 days with fatigue." Pet'r's Ex. 6 at 8, ECF No. 7-6. The record from this visit does not include any reference to shoulder pain or injury. *See id.* at 8–9. On March 29, 2016, Petitioner went to the emergency room at University of Maryland Charles Regional Medical Center for a medication refill after Walgreens would not fill a prescription. Pet'r's Ex. 4 at 28, 31–32, ECF No. 7-4. Records from this visit do not reference any shoulder issue. *See id.* at 28–35.

Petitioner returned to the ER at Charles Regional Medical Center on April 10, 2016. *Id.* at 10. Petitioner was complaining that a "piece of wire" came out of her navel that morning and reporting abdominal pain. *Id.* at 11. Petitioner told the nurse that she believed that the wire was from having her tubes tied[4] in 1990, but Petitioner could not locate the piece of wire. *Id.* In her notes, nurse Elizabeth Bailey reported that "[Petitioner] wanted this nurse to look in her belly button and 'see the open sore that the wire made when it came out.'" *Id.* at 15. Nurse Bailey continued that she "explained that she could not see any open sore. When she told [Petitioner] it was possible the wire came from someplace else [Petitioner] insisted it came from her surgery in 1990." *Id.* In a CAT scan report, Dr. Curtis Hammerman recorded his impression as "[p]robable

[3] Schizoaffective disorder is "a mental disorder in which a major depressive episode, manic episode, delusions or hallucinations, or a mixed episode occurs over an uninterrupted period of time, along with prominent psychotic symptoms characteristic of schizophrenia." Its symptoms are not due to substance use. *Schizoaffective Disorder*, DORLAND'S MEDICAL DICTIONARY ONLINE [hereinafter "DORLAND'S"], https://www.dorlandsonline.com (last visited Jan. 2, 2021). Schizophrenia is "a mental disorder characterized by various combinations of disturbances in the form and content of thought (e.g., delusions, hallucinations), in mood (e.g., inappropriate affect), in sense of self and relationship to the external world (e.g., loss of ego boundaries, withdrawal), and in behavior (e.g., bizarre or apparently purposeless behavior), which cause marked decrease in functioning." *Schizophrenia*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 2, 2021).

[4] This refers to tubal ligation, which is the "sterilization of the female by constricting, severing, or crushing the uterine tubes[. C]onstriction may be with an encircling plastic ring or other ligature." *Tubal Ligation*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 4, 2021).

bilateral adrenal adenomas."[5] *Id.* at 24. He continued that "[t]here may be a tiny appendicolith[6] present however there is no dilation of the appendix nor inflammation." *Id.* The records from this visit do not contain mention of Petitioner's shoulder. *See id.* at 10–27.

On April 27, 2016, Petitioner presented to MedStar Family Choice and reported having a cough for at least two weeks. Pet'r's Ex. 5 at 9, ECF No. 7-5. The record does not refer to Petitioner's shoulder. *See id.* at 9–11.

Petitioner presented to chiropractor Frank Alfano, D.C. ("Chiropractor Alfano") on May 11, 2016. Pet'r's Ex. 14 at 7, ECF No. 21-3; Pet'r's Ex. 14 at 1, ECF No. 23-1. In his initial evaluation of Petitioner, Chiropractor Alfano stated that Petitioner reported that she was involved in a car accident on May 6, 2016. *Id.* at 1. Petitioner told Chiropractor Alfano that her car was struck from the right and that her airbag did not deploy. *Id.* Chiropractor Alfano wrote that, "[a]t the moment of impact her body was straight. Additionally, when impact occurred, her head and neck were straight." *Id.* He continued that "[t]he force of the collision caused [Petitioner] to strike the following: her right lower extremity against the dashboard; and her left lower extremity against the dashboard." *Id.*

Chiropractor Alfano identified Petitioner's "symptoms and complaints" as pertaining to her spine and lower extremities. *Id.* at 1–2. Chiropractor Alfano reported that Petitioner had "severe, dull pain[]" in her "[n]eck (both sides)[;] . . . [u]pper [b]ack (both sides)[;] . . . [m]id [b]ack (both sides)[;] . . . [and] [l]ow [b]ack (both sides)[.]" *Id.* at 1. Chiropractor Alfano stated that these "[s]ymptoms occurred constantly and were worsening." Additionally, Chiropractor Alfano noted that Petitioner had "moderate, dull pain[]" in her "[k]nee (left side)[]" and "[k]nee (right side)[.]" *Id.* at 2. Chiropractor Alfano wrote that "[s]ymptom[s] occurred constantly and w[ere] worsening." *Id.* He continued, writing that Petitioner "reported that her symptoms began suddenly 5/6/16 and were consistent in severity throughout the day." *Id.* Petitioner rated her pain as an 8 on a "scale of 0 to 10 (with 0 being the absence of pain and 10 being the worst pain possible)[.]" *Id.* Chiropractor Alfano noted that Petitioner had been evaluated and treated for these conditions by an urgent care facility. *Id.* He also stated, "[b]y the patient's own account, her neck and low back complaints have existed in her medical history." *Id.*

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[5] An adenoma is "a benign epithelial tumor in which the cells form recognizable glandular structures or in which the cells are clearly derived from glandular epithelium." *Adenoma*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). "Glandular" "pertain[s] to or of the nature of a gland[,]" and "epithelium" refers to "the covering of internal and external surfaces of the body, including skin and the lining of body cavities, hollow organs, vessels and ducts[]" and "consists of one or more layers of cells joined by small amounts of cementing substances." *Glandular*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Epithelium*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). Adrenal means "pertaining to either of two glands located just above the kidneys[]" while bilateral means "having two sides[] or pertaining to both sides." *Adrenal*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Bilateral*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[6] An appendicolith is "a calculus in the vermiform appendix." *Appendicolith*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). The vermiform appendix, also called the appendix or the cecal appendix, is "a wormlike diverticulum of the cecum[.]" *Vermiform Appendix*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

Chiropractor Alfano reported that "[a] review of systems was significant for the following reported conditions or problems: [c]ontinued loss of sleep[;] [n]ervousness, anxiety, and depression[; and] [c]hronic cough." *Id.* at 3. The "Review of Systems" also included a note that Petitioner indicated she was not pregnant." *Id.* Chiropractor Alfano also performed a neurological assessment and a spinal examination/orthopedic assessment. In Chiropractor Alfano's report from the spinal examination, he noted a negative Soto Hall test and wrote that "[t]he shoulder depression test produced a negative response bilaterally. *Id.* at 4. Petitioner's response to the shoulder depression test is the only reference to Petitioner's shoulder in her chiropractic records. *Id.* at 21; *see also id.* at 1–22. There is, however, no indication that such a test would have revealed Petitioner's shoulder injury. Following this assessment, Chiropractor Alfano listed Petitioner's "[p]rimary [d]iagnos[e]s" as "[s]prain of ligaments of cervical spine[,]"[7] "[s]prain of ligaments of thoracic spine[,]"[8] and "[s]prain of ligaments of lumbar spine[.]"[9] *Id.* at 4–5. Chiropractor Alfano did not diagnose Petitioner with any shoulder ailment. *See id.*

Petitioner returned to Chiropractor Alfano on May 24, May 26, May 31, June 6, June 14, and June 21, 2016. See *id.* at 9–19. Throughout these appointments, Petitioner complained of pain in her lower back, middle back, upper back, neck, and/or knees but not in her shoulder. See *id.* By her last appointment on June 21, 2016, Chiropractor Alfano documented that Petitioner only complained of intermittent, dull pain in her left lower back and in the right side of her neck. *Id.* at 19–20. In a note he wrote on June 23, Chiropractor Alfano wrote that "[a]s of this re-examination, [Petitioner] reported that since her previous exam, she had no new injuries, accidents, or illnesses that could have aggravated her original complaints or caused any new complaints. [Petitioner] additionally related that she had no treatments or examinations outside of this office for her condition." *Id.* at 20.

Petitioner returned to MedStar Family Choice on May 23, 2016. Pet'r's Ex. 5 at 6. Dr. Helen Norwood noted that Petitioner "came to the office for medication renewal." *Id.* The note states that Petitioner "continues to have a cough. She is concern [sic] because she was concerned that she was informed that she has black mold in her home." *Id.* The record does not discuss Petitioner's shoulder. *See id.* at 6–9.

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[7] The cervical spine is "the part of the spine comprising the cervical vertebrae[,]" which is "the upper seven vertebrae, constituting the skeleton of the neck." *Cervical Spine*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Cervical Vertebrae*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[8] The thoracic spine is "the part of the spine comprising the thoracic vertebrae[,]" which is "the vertebrae, usually twelve in number, situated between the cervical and lumbar vertebrae, giving attachment to the ribs and forming part of the posterior wall of the thorax [also known as the chest]." *Thoracic Spine*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Thoracic Vertebrae*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Thorax*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[9] The lumbar spine is "the part of the spine comprising the lumbar vertebrae[,]" which is "the five vertebrae between the thoracic vertebrae and the sacrum." *Lumbar Spine*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Lumbar Vertebrae*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Vertebrae Lumbales*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). The sacrum is "the triangular bone just below the lumbar vertebrae[.]" *Sacrum*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

On May 28, 2016, Petitioner presented to Dr. Michelle Pyka at University of Maryland Charles Regional Medical Center emergency department complaining of shoulder pain. Pet'r's Ex. 4 at 1, ECF No. 7-4. The triage nurse wrote that Petitioner presented "with pain in shoulder and right arm[]" and that Petitioner stated "this is where she had [Hepatitis B] shot[.]" *Id.* at 3. The nurse recorded that Petitioner appeared "[i]n [p]ain[.]" *Id.* Both the triage assessment and bedside assessment listed Petitioner's "Pain Level[]" as "5[.]" *Id.* According to "Patient Notes" from Petitioner's visit, Petitioner came to the emergency department with right upper arm and shoulder pain that, according to Petitioner, had lasted more than two months, since Petitioner received the Hepatitis B vaccine. *Id.* at 5. The note says, "right upper arm soft, no bruising noted. strong radial pulse." *Id.* According to the note, Petitioner was "using arm freely[]" but was given a sling. *Id.* Petitioner was prescribed Tylenol #3 (Acetaminophen/Codeine).[10] *Id.* at 1. The record suggests that Petitioner was diagnosed with rotator cuff[11] injury and shoulder sprain. *See id.* at 6; *see also* Pet'r's Ex. 5 at 27. Petitioner received instructions to follow up with her primary care physician and an orthopedist. *Id.*

Petitioner visited Dr. Mark Henderson at Southern Maryland Orthopaedic & Sports Medicine Center on June 6, 2016. Pet'r's Ex. 17 at 5, ECF No. 35-1. Petitioner complained of right shoulder pain. *Id.* The "Subjective Transcription" from the visit states that Petitioner "comes in today states [sic] that Percocet[12] works for pain and that is all she wants." *Id.* The note records that Petitioner "said that chiropractor in La Plata can cure this, and she will see him. She is wearing a sling and use it [sic] since the May 28th [emergency room] visit." *Id.* The "Objective Transcription" records that Petitioner was able to reach "about 165 degrees of forward flexion[]"[13] without the sling. *Id.* at 6. The provider noted that there was not "a dramatic amount of swelling[]" and that Petitioner was "neurovascularly intact distally." *Id.* The "Assessments Transcription" states, "Right shoulder pain status post [H]epatitis B injection." *Id.* Dr. Henderson reported that Petitioner was "really unclear today and poor historian in term of the exact time when she got the shot, although she states it was about two months ago." *Id.* He noted that Petitioner was insistent "on getting some type of medication-probably Percocet or Tylenol with Codeine." *Id.* Dr.

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[10] Acetaminophen is "the amid of acetic acid and p-aminophenol[]" and has "analgesic and antipyretic effects . . . but only weak anti-inflammatory effects." *Acetaminophen*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). Codeine is "a narcotic alkaloid obtained from opium or prepared by methylating morphine[,]" which is "the principal and most active opioid alkaloid of opium . . . ." *Codeine*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Morphine*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[11] The rotator cuff is "a musculotendinous structure about the capsule of the shoulder joint, formed by the inserting fibers of the supraspinatus, infraspinatus, teres minor, and subscapularis muscles, blending with the capsule and providing mobility and strength to the shoulder joint." *Rotator Cuff*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[12] Percocet is a "trademark for a combination preparation of oxycodone hydrochloride and acetaminophen." *Percocet*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). Oxycodone hydrochloride is an analgesic and "the hydrochloride salt of oxycodone[,]" which is "an opioid agonist analgesic derived from morphine." *Oxycodone Hydrochloride*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Oxycodone*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[13] Flexion refers to "the act of bending or condition of being bent." *Flexion*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

Henderson prescribed Petitioner Skelaxin[14] for muscle spasms and instructed her to follow up as needed. *Id.* at 4, 6. The record also indicates that the office prescribed Petitioner Ultracet[15] on June 9, 2016. *Id.* at 3.

On June 22, 2016, Petitioner visited Dr. Helen Norwood at MedStar Family Choice. Pet'r's Ex. 5 at 4. The "Encounter Reason/Date" is listed as "pain in right shoulder and right knee (she thinks it came from b12 shot)" and refills. *Id.* Dr. Norwood wrote that "[t]his is a 48 year old [sic] woman who came to the office reporting having pain in her right shoulder and and [sic] right knee. The pain occurred after the patient obtained an injection." *Id.* Dr. Norwood continued, "[s]he went to an Urgent Care Facility for an evaluation. She was placed on naprosen [sic] [("Naproxen")],[16] but the medication is not adequately controlling the patient's pain. She [came] to the office today because the pain in her shoulder has not improved." *Id.* Following the physical exam, Dr. Norwood noted that Petitioner had tenderness and limited range of motion in her right shoulder as well as tenderness in her right knee. *Id.* Dr. Norwood prescribed Petitioner Percocet for her shoulder pain and provided her an orthopedic referral for her shoulder and knee pain. *Id.* at 4–5.

Petitioner returned to MedStar on July 27, 2016, for nausea, vomiting, and headache as well as medication refills. *Id.* at 1. The physical exam indicated that Petitioner was experiencing shoulder tenderness. *Id.* at 2. Dr. Norwood prescribed Petitioner lidocaine[17] 5% topical ointment for her shoulder pain and issued a pain management referral. *Id.*

Petitioner visited Patient First – Waldorf on October 2, 2016, complaining of right arm and left hip pain. Pet'r's Ex. 6 at 10, ECF No. 7-6. The record indicates that Petitioner was complaining about right arm pain that she believed "to have been from MVA in March as well as [H]epatitis B vaccination." The provider noted that Petitioner attributed her left hip pain to her "MVA from March 2016." *Id.* Petitioner reported no numbness or tingling but a physical exam revealed "[d]ecreased ROM of upper extremity." *Id.* The provider noted that Petitioner was "only able to abduct arm to 90 degrees." *Id.* The provider commented that Petitioner was suffering from musculoskeletal pain, which "[m]ay be secondary to MVA." *Id.* at 11. The provider advised

[14] Skelaxin is a "trademark for a preparation of metaxalone[,]" which is "a centrally acting skeletal muscle relaxant used in the treatment of painful musculoskeletal conditions . . . ." *Skelaxin*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Metaxalone*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[15] Ultracet is a "trademark for a preparation of tramadol hydrochloride and acetaminophen." *Ultracet*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). Tramadol hydrochloride is "an opioid analgesic used for the treatment of moderate to moderately severe pain following surgical procedures and oral surgery[.]" *Tramadol Hydrochloride*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[16] Naproxen is "a nonsteroidal antiinflammatory drug that is a propionic acid derivative[]" and that is "used in the treatment of pain, inflammation, [and other conditions.]" *Naproxen*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 4, 2021)

[17] Lidocaine is a topically-applied drug with "anesthetic, sedative, analgesic, anticonvulsant, and cardiac depressant activities[]" that is "used as a local anesthetic . . . ." *Lidocaine*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

Petitioner to use Motrin[18] and Voltaren[19] gel. *Id.* An addition to the record dated October 12, 2016, indicates that Petitioner called the office upset and seeking a referral to physical therapy but that the practice was unable to provide her one. *Id.* During the call, Petitioner stated "that her arm hurts from a Hepatitis B vaccine she got and her hip from a[n] MVA she had in May." *Id.*

On October 14, 2016, Petitioner met with Dr. Mario Nicholson at GBMS-Brandywine Health Center. Pet'r's Ex. 7 at 1, ECF No. 7-7. Dr. Nicholson wrote that Petitioner had "Chronic R-shoulder pain for several months[]" and that Petitioner felt "it was 'due to Hepatitis B vacination [sic].'" *Id.* Petitioner reported that she had been taking pain medication and receiving treatment from "Ortho." *Id.* Dr. Nicholson also recorded, "[s]tates pain with abdution [sic], internal and external rotation. At night. Pain entire shoulder, sharp 9/10." *Id.* At Petitioner's request, Dr. Nicholson gave Petitioner a referral to physical therapy. *Id.* Dr. Nicholson noted that Petitioner was "not able to provide time duration for shoulder pain, last visit with her HTN PCP, etc." *Id.*

Petitioner presented for physical therapy at Winters Chiropractic & Physical Therapy on October 20, 2016. Pet'r's Ex. 8 at 10, ECF No. 7-8. She filled out a "Registration and History" form that day. *See id.* at 13. In the space labeled "[r]eason for visit[,]" she wrote, "pain in right arm due to hepititas [sic] B shot[.]" *Id.* at 14. In the blank entitled "[w]hen did your symptoms appear[,]" she wrote "[two] days after they gave me the shot[.]" *Id.* Petitioner rated the severity of her pain on a scale from 1 (least pain) to 10 (severe) as "10[.]" *Id.* In "[t]ype of pain[,]" she checked spaces next to "[s]harp" and "[a]ching" and circled "[t]hrobbing" and "[s]tiffness[.]" By "[a]ctivities or movements that are painful to perform[,]" she checked spaces next to "[s]itting[,]" "[s]tanding[,]" "[w]alking[,]" and "[l]ying down[.]" She reported that she experiences this pain "[e]veryday" and that it interfered with her "[w]ork[,]" "[s]leep[,]" and "[d]aily [r]outine[.]" *Id.* She reported that she had never had chiropractic care for any other problems. *Id.* Petitioner returned for additional physical therapy appointments on October 25, October 27, November 1, and November 3, 2016. *Id.* at 5–12.

Petitioner visited Dr. Nicholson on December 15, 2016. Pet'r's Ex. 18 at 18, ECF No. 35-2. Dr. Nicholson recorded that "P[etitioner] thinks that Clonazepam[20] has been causing [m]emory

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[18] Motrin is a "trademark for preparations of ibuprofen." *Motrin*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). Ibuprofen is "a nonsteroidal antiinflammatory drug derived from propionic acid and also having analgesic and antipyretic actions[.]" *Ibuprofen*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). Nonsteroidal antiinflammatory drugs, or NSAIDs, consist of a "chemically heterogeneous group of drugs that inhibit cyclooxygenase activity, resulting in decreased synthesis of prostaglandin and thromboxane precursors from arachidonic acid[]" and all have "analgesic, antipyretic, and antiinflammatory actions." *Nonsteroidal Antiinflammatory Drug*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[19] Voltaren is a "trademark for preparations of diclofenac sodium[,]" which is "administered orally . . . for a variety of nonrheumatic inflammatory condition[,]" as well as for other conditions, and is "also applied topically . . . to the skin to treat keratoses[]" or to the eye. *Voltaren*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021); *Diclofenac Sodium*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021). Actinic keratosis is "a sharply outlined, red or skin-colored, flat or elevated, verrucous or keratotic growth that sometimes develops into a cutaneous horn or gives rise to a squamous cell carcinoma." *Actinic Keratosis*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[20] Clonazepam is "a benzodiazepine used . . . as an antipanic agent in the treatment of panic disorders." It is also used as an anticonvulsant. *Clonazepam*, DORLAND'S, https://www.dorlandsonline.com (last visited

problems, confusion, diarrhea, headache, slurred speech and fatigue for many years[]" and that Petitioner was seeking to stop taking the medication. *Id.* On January 10, 2017, Petitioner visited Dr. Nicholson at GBMS reporting that she had visited the emergency room for "HA, memory problems and insomnia." *Id.* at 15. Petitioner confirmed in a status report submitted on December 3, 2018, that she "suffers from significant mental illness and memory issues." ECF No. 36 at 2.

Petitioner also produced records from CVS and Walgreens pharmacies. *See* Pet'r's Exs. 20–21, ECF Nos. 47-1–47-2. Many medications are included in the records. *See id.* Relevant to this matter, the records show that Petitioner filled prescriptions for Naproxen on June 11, 2016, and January 25, 2016. Pet'r's Ex. 20 at 2; Pet'r's Ex. 21 at 5. The record also indicates that Petitioner had a prescription for Naproxen since December 1, 2015. *See* Pet'r's Ex. 21 at 5. This medication is pertinent because, in her declaration, Petitioner asserted that she visited her "local urgent care" and saw a provider named Dr. Olasimbo "[s]hortly after" her vaccination. Pet'r's Ex. 1 ¶ 7, ECF No. 7-1. Petitioner continued in her declaration that Dr. Olasimbo prescribed Petitioner Naproxen during this visit for her post-vaccination pain. *Id.* Petitioner's claim that she visited a local urgent care facility after her vaccination and was prescribed Naproxen at that time is supported by her statements to Dr. Norwood on June 22, 2016. *See* Pet'r's Ex. 5 at 4. However, records from Petitioner's visit with Dr. Olasimbo are unavailable. Petitioner attempted to subpoena records from "MyDoctor Urgent Care[,] . . . where Petitioner was prescribed Naproxen for her shoulder pain after receiving her vaccination." Status Report, ECF No. 31 at 1. Petitioner was unsuccessful because "this office has closed and the response to the subpoena has not been returned." *Id.*

The pharmacy records submitted by Petitioner are inconsistent with the notion that she was prescribed Naproxen in relation to her vaccination. Although they show that Petitioner has been prescribed Naproxen before, they do not indicate that Petitioner filled prescriptions for the medication in March or April 2016 or from Dr. Olasimbo. *See* Pet'r's Ex. 20 at 2; Pet'r's Ex. 21 at 3–13. Further, the CVS record shows that Petitioner filled various prescriptions, including one prescription for cyclobenzaprine[21] and one prescription for ibuprofen[22] 800 mg tablets, issued by a provider named Olayi O. Olasimbo during May and June 2016. Pet'r's Ex. 20 at 2. It is unclear whether some of the prescriptions are refills. *See id.* Although the record shows that Petitioner filled prescriptions in March and April 2016, the record does not show that Petitioner filled any prescriptions from Dr. Olasimbo during those months. *See id.*

B. Petitioner's Declarations and Witness Declarations

Petitioner submitted a declaration on June 7, 2017. Pet'r's Ex. 1. In her declaration, Petitioner stated that on March 23, 2016, she received the Hepatitis B vaccine in her right shoulder. *Id.* ¶ 5. She asserted that she did not have any issues with her right shoulder prior to this vaccination. *Id.* ¶ 4. Petitioner recalled experiencing "instantaneous and severe" pain when

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Jan. 3, 2021). Benzodiazepines function as "depressants of the central nervous system, their actions including antianxiety, sedative, hypnotic, amnestic, anticonvulsant, and muscle relaxing effects." *Benzodiazepine*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 3, 2021).

[21] Cyclobenzaprine hydrochloride is "a compound structurally related to the tricyclic antidepressants, used as a skeletal muscle relaxant for relief of painful muscle spasms[.]" *Cyclobenzaprine Hydrochloride*, DORLAND'S, https://www.dorlandsonline.com (last visited Jan. 4, 2021).

receiving the vaccination. *Id.* ¶ 6. When feeling pain upon commencement of the injection, Petitioner "remember[ed] screaming 'ouch' and the nurse telling [her] that [Petitioner] was a big girl and could take the pain." *Id.*

Petitioner recalled visiting Dr. Olasimbo at an urgent care facility following her vaccination and being prescribed Naproxen. *Id.* ¶¶ 7–8. Petitioner noted that she explained to Dr. Olasimbo that her "pain started immediately while being given the Hepatitis B shot." *Id.* ¶ 7. Petitioner recalled managing her pain by taking Naproxen, prescribed by Dr. Olasimbo, and by regularly applying ice and heat packs to her shoulder. *Id.* ¶¶ 7–8. Petitioner proceeded to reaffirm some of the information in her medical records pertaining to her complaints of and treatments for shoulder pain. *See id.* ¶¶ 9–11, 13–15. Adding to the information in her medical records, Petitioner stated that upon presenting at the emergency room on May 28, 2016, she "had constant aching pain and difficulty lifting [her] arm and driving." *Id.* ¶ 9. She added that when she went to MedStar Health on June 22, 2016, she "explained that [her] symptoms had not improved" and that she "was still in significant pain." *Id.* ¶ 10. Petitioner also indicated that between her July 27, 2016 visit to MedStar Health and her October 2, 2016 visit to Patient First, *see id.* ¶¶ 11–13, she "continued to take pain medication regularly for [her] right shoulder pain for the next couple of months" but that "[u]nfortunately, the pain remained." *Id.* ¶ 12. Petitioner asserted that her "right shoulder injury from the Hepatitis B vaccination . . . lasted for over six months." *Id.* ¶ 16. She stated that she "has had minimal pain since going to physical therapy." *Id.* Petitioner stated that between receiving the vaccination and commencing physical therapy, her "injury affected [her] on a daily basis." Id ¶ 17. Petitioner reported that she "had constant aching pain and was unable to do many chores around the house without pain[]" and that she "had pain when [she] had to lift [her] arm or carry heavier items like laundry." *Id.* She also noted that she "had pain when [her] arm was outstretched while driving." *Id.* She stated that she had "largely recovered since having physical therapy and no longer require[d] taking daily pain medication for [her] right shoulder pain." *Id.*

Following concerns regarding her 2016 MVA, *see* Resp't's Report at 4, Petitioner submitted a supplemental declaration on July 3, 2018, regarding her accident and subsequent treatment. Pet'r's Ex. 15, ECF No. 24. In her supplemental declaration, Petitioner stated that her car was struck on its right side in a grocery store parking lot on May 6, 2016, but that the airbag did not deploy. *Id.* ¶¶ 2–4. Petitioner claimed that the accident caused back, neck, and knee pain. *Id.* ¶ 5. She stated that, to file an insurance claim, she retained a personal injury lawyer, who referred her to Chiropractor Alfano for chiropractic injury treatment. *Id.* ¶¶ 6–7. Petitioner stated that Chiropractor Alfano only treated her for the injuries stemming from her accident: back, neck, and knee pain. *Id.* ¶¶ 8–9. Petitioner asserted that she "did not hurt [her] right shoulder in the car accident[]" and maintained that her "right shoulder injury was from the Hepatitis B shot [she] got on March 23, 2016." *Id.* ¶¶ 10–11. She stated that "[Chiropractor] Alfano did not treat [her] for [her] shoulder injury[,]" and that she "did not discuss [her] right shoulder pain with [him,] because [her] shoulder pain was not related to the car accident." *Id.* ¶¶ 12–13.

In support of her claim, Petitioner submitted declarations of her daughters, L.W.1 and L.W.2, on June 20, 2018. Pet'r's Exs. 11–12, ECF Nos. 21-1–21-2. In her declaration, signed on April 18, 2018, L.W.1 stated that Petitioner "informed [her] within a few days after [Petitioner] received a Hepatitis B vaccine in [Petitioner's] left shoulder, that it was painful." Pet'r's Ex. 11 ¶ 5. L.W.1 noted that Petitioner reported that "they were rough when they inserted the needle and that her arm hurt." *Id.* L.W.1 stated that "[t]he pain began immediately after the vaccination." *Id.*

L.W.1 recalled that Petitioner's complaints to her about Petitioner's arm pain following the vaccination continued for about six to seven months after Petitioner received the vaccine. *Id.* ¶ 6. L.W.1 reported that Petitioner was still experiencing some shoulder pain. *Id.* ¶ 7. She stated that she spoke to Petitioner "almost every other day on the telephone" and that Petitioner "occasionally brings up her arm pain when we speak." *Id.*

In her declaration also signed on April 28, 2018, L.W.2 stated that she lives in California but that she previously lived in Waldorf, Maryland, about five minutes away from Petitioner. Pet'r's Ex. 12 ¶¶ 3, 5. L.W.2 recalled that Petitioner "called [her] in 2016 to report [Petitioner] was experiencing shoulder pain after receiving a vaccine" about a week earlier. *Id.* ¶ 6. L.W.2 stated that "[t]he pain was in the same area where [Petitioner] received the vaccine." *Id.* L.W.2 recalled observing that Petitioner "could not lift her arm too high" and having to assist Petitioner with hanging up clothes. *Id.* ¶ 7. She also noted that "[a] few months later, [L.W.2] had to help [Petitioner] get [Petitioner's] curtains down because [Petitioner] could not reach too high with her arm above her head." *Id.* L.W.2 stated that Petitioner complained "for some time about her shoulder pain" and told L.W.2 that Petitioner "could not sleep on her right side." *Id.* ¶ 8. L.W.2 stated, "I speak to [Petitioner] about five to six . . . times per day. Occasionally, she still complains about her continued shoulder pain." *Id.* ¶ 10. L.W.2 claimed that though Petitioner's "condition has somewhat improved[,]" Petitioner "still experiences pain." *Id.* ¶ 9.

In response to my final request for evidence, Petitioner submitted declarations of her friend T.T. and her husband, D.C., on October 3, 2019. Pet'r's Exs. 22–23, ECF Nos. 47-3–47-4. In her declaration signed on October 2, 2019, T.T. stated that she became friends with Petitioner after meeting her through Petitioner's son and that she regularly visited Petitioner when Petitioner lived about five minutes away from her in Waldorf, Maryland. Pet'r's Ex. 22 ¶ 5–6. T.T. recalled that "in late March 2016, [she] went over to [Petitioner's] house" to celebrate Petitioner's belated birthday. *Id.* ¶ 7. T.T. noted that she "believe[d] it was the weekend after [Petitioner's] actual birth date." *Id.* T.T. reaffirmed that while she was "not sure of the exact date of her visit, . . . it was the weekend following [Petitioner's] birthday in March 2016." *Id.* ¶ 8. T.T. stated that, "[a]t that time, [Petitioner] complained to [T.T.] about the soreness and tenderness [Petitioner] felt in her upper arm after receiving a vaccination a few days earlier. [Petitioner] said that she had been having difficulty sleeping on her arm since the vaccination." *Id.* ¶ 7. T.T. reported that Petitioner mentioned her continuing shoulder pain when T.T. spoke to Petitioner "a few times after [the belated birthday celebration] in the spring of 2016." *Id.* ¶ 9. T.T. stated that she remembered this because "[T.T.] thought it was unusual that a person would continue to have shoulder pain months after receiving a vaccination." *Id.*

In his declaration also signed on October 2, 2019, Petitioner's husband, D.C., stated that "[t]he day after [Petitioner] received a [H]epatitis B shot she complained her arm was hurting." Pet'r's Ex. 23 ¶ 6, ECF No. 47-4. He recalled accompanying Petitioner to "Urgent Care" "[w]ithin about seven to ten days[.]" *Id.* D.C. stated that Petitioner "saw a doctor who gave her medication for her shoulder pain." *Id.* D.C. noted that [Petitioner's] shoulder pain continued for several months." *Id.* ¶ 7. He recalled that "[d]uring this time [Petitioner] had problems lifting her arm and sleeping on her right arm." *Id.* D.C. noted that Petitioner "later attended physical therapy." *Id.*

III. Applicable Legal Standard

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) that the petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

Petitioner argues that she is entitled to compensation because her receipt of the Hepatitis B vaccine caused her to sustain a Table injury, SIRVA. The Vaccine Injury Table considers SIRVA a presumptive injury for the Hepatitis B vaccine if the first symptom or manifestation of onset of the illness occurs within forty-eight hours of an intramuscular vaccine administration. *See* 42 C.F.R. § 100.3(a)(XIV). The Qualifications and Aids to Interpretation ("QAI") further specify:

> A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
> ii) Pain occurs within the specified time-frame;
> iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
> iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10). The QAI also explain that "SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm." *Id.* The QAI specify that "[t]hese symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction." *Id.* If this Court does not find that Petitioner suffered a Table injury as described above, Petitioner alternatively claims that her injury was caused-in-fact by the Table vaccine in question.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. 42 U.S.C. § 300aa-13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between

vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program on the basis of causation-in-fact, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994).

IV. Arguments Regarding Entitlement

A. Petitioner's Arguments

Petitioner argues that she is entitled to compensation because she satisfies the criteria to establish a SIRVA Table injury or, alternatively, because she has sufficiently established that her injury was caused-in-fact by her Hepatitis B vaccination. Pet'r's Br. at 1, 10, 14, ECF No. 50. Petitioner states that "[t]he main issue in this case is onset and being able to directly pinpoint when Petitioner's pain began." *Id.* at 15. She claims that "[t]he evidence that has been provided shows that Petitioner's pain began after receiving the Hepatitis B vaccination." *Id.*

Petitioner first argues that "Petitioner has satisfied all elements of a SIRVA claim that presumes causation." *Id.* at 10. Petitioner argues that her claim fulfills the first criterion of a SIRVA Table claim because "Petitioner did not have a history of pain, inflammation, or dysfunction of her right shoulder prior to receiving the . . . vaccination that would explain her post-vaccination symptoms and findings." *Id.* at 11. Petitioner adds that "Petitioner never had any problems with her right shoulder before receiving the . . . vaccination." *Id.* In support of this position, Petitioner states that her prior medical conditions included "anxiety, obesity, hypertension, hyperlipidemia, and GERD" as well as mental illness. *Id.* (citing Pet'r's Ex. 1 ¶ 3; Pet'r's Ex. 16). Although this is not an exhaustive list of Petitioner's prior medical conditions, Respondent does not dispute Petitioner's satisfaction of the first criterion. *See generally* Resp't's Report; Resp't's Br.

Petitioner asserts that her injury fulfills the second criterion because her "pain began immediately after receiving the . . . vaccination." *Id.* at 11–12. To support her assertion, Petitioner cites her declaration, in which she recounted experiencing, and immediately conveying that she was experiencing, "instantaneous and severe" pain. *Id.* at 11. Petitioner also maintains that her submitted witness declarations "show Petitioner complained about her right shoulder pain following receipt of the Hepatitis B vaccination." *Id.* at 13. Petitioner also cites to the medical records to support this assertion. *See id.* at 12–13 (referencing records from Petitioner's May 28, June 6, June 22, October 2, October 14, and October 20, 2016 appointments). She claims that "[a]lthough [her] documented treatment was delayed, when she did report her right shoulder pain[,] she related it back to her Hepatitis B vaccination." *Id.* at 13.

Petitioner claims that she has established the third criterion because her "pain and reduced range of motion[,]" documented in the medical records, "was limited to her right shoulder." *Id.* at 13–14. Petitioner notes that "[a]lthough she complained of various non-SIRVA related ailments, no other issues or injuries were ever attributed to her Hepatitis B vaccination[]" and that "Petitioner only attributed her right shoulder pain to the Hepatitis B vaccination." *Id.* at 14.

Petitioner argues that her claim fulfills the fourth criterion because "Petitioner's medical providers diagnosed her with classic SIRVA diagnoses and no alternative causes for her right shoulder injury were ever provided. In fact, none exist." *Id.* Petitioner notes that she presented to various practitioners with her right shoulder pain and that she "never exhibited symptoms that would cause her practitioners to believe she was suffering from another condition or abnormality." *Id.* Petitioner adds that "[n]o medical provider believed that Petitioner had radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy." *Id.*

As an alternative to her Table claim, Petitioner argues that she has satisfied the three *Althen* prongs, *id.* at 14 (citing *Althen*, 418 F.3d at 1278–80), and has thus established that the vaccination "caused-in-fact" her injury. *Id.* Regarding the first prong, Petitioner asserts that she has "provided sufficient evidence to show she received the Hepatitis B vaccination and stated in her declaration that her pain was immediate." *Id.* at 14–15. Petitioner cites to her declaration, in which she remembered "screaming out in pain as a result of her vaccination and speaking with the nurse about it." *Id.* at 15. Petitioner argues that "[i]mproper administration of a vaccination is a medical theory that connects the vaccination and injury." *Id.* Regarding the second prong, Petitioner claims that she has "showed a logical sequence of cause and effect because she had worsening pain for which she sought pain medication at an urgent care." *Id.* She argues that the medical records, her declarations, and witness declarations show that "[v]arious witnesses recounted that Petitioner developed pain after" the vaccination. *Id.* Petitioner also notes that she "told numerous providers that her right shoulder pain began following" the vaccination. *Id.* Petitioner asserts that "the evidence supports a logical sequence of cause and effect." *Id.* Regarding the third prong, Petitioner argues that a proximate temporal relationship exists because "Petitioner reported her injury approximately two months after receiving the vaccination and related it back to being caused by the Hepatitis B vaccination." *Id.* She further argues that such a relationship exists because "[o]n multiple occasions Petitioner explained that her right shoulder pain began after receiving the . . . vaccination." *Id.*

Furthermore, Petitioner writes that "[t]he analysis in this case is overshadowed by mental health problems and a lack of consistent medical providers." *Id* at 3. She argues that "[a]ny silence in Petitioner's records in regards to the onset of her pain should be attributed to the severity of Petitioner's claim, not its validity." *Id.* Petitioner notes that she has long been taking antipsychotic medication to treat schizoaffective disorder. *Id.* She claims that "[h]er mental illness has hindered her ability to maintain consistent medical providers and receive adequate treatment for various medical issues." *Id.* Petitioner maintains that "she is a credible individual" despite the fact that she "suffer[s] from mental illness and foggy memory[.]" *Id.* In support of her credibility, Petitioner asserts that "the entirety of Petitioner's vaccine claim[]" demonstrates that she "was consistent in asserting that her right shoulder pain was caused by the Hepatitis B vaccination." *Id.*

Petitioner acknowledges that, due to its closure, she was unable to obtain records from MyDoctor Urgent Care, which she claims to have visited within days of her vaccination. *Id.* at 4. Instead, she highlights that the available records establish that she reported to later providers that she had visited an urgent care facility for her shoulder pain post vaccination. *See id.* at 4–5. Petitioner also discusses her various visits to medical offices for issues other than shoulder pain. *See id.* at 6–7. Petitioner admits that "[i]n the approximate two months between receiving the Hepatitis B vaccination and complaining about her shoulder injury formally to a medical provider, Petitioner visited three different medical facilities for general internal medicine issues." *Id.* at 7. Petitioner continues, stating that she "does not have a regularly [sic] primary care doctor" and that

she "lacks consistent medical care with a single provider." *Id.* Petitioner states that "she goes to various urgent cares and emergency rooms for her treatment as needed[]" and that "[t]his jumble of medical treatment severely impacts Petitioner's ability to receive thorough health care." *Id.* Petitioner also mentions that she did not injure her right shoulder in her May 6, 2016 MVA or receive chiropractic care for said shoulder during her May and June 2016 chiropractic appointments. *Id.*

Petitioner further notes that her four witness declarations corroborate that "Petitioner complain[ed] about her right shoulder pain soon after" the vaccination. *Id.* at 3. Petitioner, noting that her daughters are financially independent adults, asserts that her husband is the only declarant with a vested interest in her claim. *Id.* at 7–8. Petitioner argues that "[a]ll of the declarations are credible and significant in showing that Petitioner's right shoulder injury was caused by her Hepatitis B vaccination." *Id.* at 8. Petitioner claims that "[a]ll of the declarations are important because they help solidify Petitioner's assertion that the Hepatitis B vaccination caused her right shoulder injury." *Id.* at 10. She continues that "[t]hese declarations are useful in shedding light on how Petitioner acted soon after receiving the vaccination." *Id.*

B. Respondent's Arguments

Respondent argues that Petitioner's claim is not appropriate for compensation, stating that, "[r]egardless of whether this claim is analyzed in an on- or off-Table context, [P]etitioner has not shown by preponderant evidence that her [H]epatitis B vaccination caused her to suffer a right-sided shoulder injury." Resp't's Br. at 7, ECF No. 49. Respondent asserts that "[P]etitioner's contemporaneous medical records demonstrate that the onset of her purported shoulder injury was at least two months post-vaccination." *Id.* To support this assertion, Respondent notes that Petitioner "had no fewer than four medical assessments between her immunization on March 23, 2016, and when she first reported right shoulder pain on May 28, 2016." *Id.* Respondent argues that not only is "[t]his time period well outside a medically appropriate interval to ascribe causation to the vaccine[,]" but that "[t]he months-long gap casts doubt upon both the development of right shoulder pain shortly after [P]etitioner's vaccination and the accuracy of her recollections." *Id.* Respondent further notes that the medical records include suggestion that her right shoulder pain stemmed from her May 2016 MVA. *Id.* at 7–8. Additionally, Respondent points out that "[P]etitioner only linked her right shoulder injury to her [H]epatitis B vaccination on May 28, 2016 – *after* her [MVA]." *Id.* at 8 (emphasis in original).

Respondent further notes that "Petitioner has not provided an expert report or other reliable medical evidence to support her claim under the *Althen* prongs." *Id.* Respondent asserts that only Petitioner, rather than "any of her numerous medical providers[,] raised the possibility that her shoulder injury" stemmed from the vaccination. *Id.* Respondent argues that "Petitioner's subjective reports to her treating providers should not be confused with a reliable medical opinion simply because they are memorialized in her records." *Id.* Citing Petitioner's own December 3, 2018 status report, Respondent notes that Petitioner admits "significant mental illness and memory issues." *Id.* Respondent continues that "[a] Special Master may not award compensation 'based on the claims of a petitioner alone, unsubstantiated by medical records or by a medical opinion.'" *Id.* (quoting 42 U.S.C. § 300aa-13(a)(1)). Respondent claims that "taken as a whole, any records suggesting a causal relationship between [P]etitioner's" vaccination and injury "amount to no more than her claims alone[.]" *Id.* Respondent concludes that "[P]etitioner has provided no reliable evidence to demonstrate that" the vaccine "caused her right-sided shoulder injury." *Id.*

V. Discussion

A. Six Month Requirement

As a preliminary matter, Petitioner must establish that she suffered from her alleged shoulder injury for at least six months as a condition precedent to consideration of injury causation. *See* 42 U.S.C. § 300aa-11(c)(1)(D). Petitioner asserts that she initially complained of shoulder pain to family members immediately following vaccination, despite a lack of any indication in her medical records that she complained to a medical professional. Petitioner's failure to seek medical attention for her shoulder pain differs from Petitioner's reaction to the pain that she complained of following her MVA. Petitioner's medical records indicate that she sought chiropractic treatment as soon as five days following her MVA, albeit for different areas of the body. Following his May 11, 2016 assessment of Petitioner, Chiropractor Alfano reported that Petitioner was experiencing pain in her neck, upper back, mid back, and low back as well as pain in her knees following a May 6, 2016 MVA. Pet'r's Ex. 14 at 1–2. Petitioner further complained of knee pain at MedStar Family Choice on June 22, 2016. Pet'r's Ex. 5 at 4–5. On October 2, 2016 at Patient First – Waldorf, Petitioner complained of left hip pain and right arm pain. Pet'r's Ex. 6 at 10–11.

Despite these different approaches to complaints of pain, Petitioner contends that the shoulder pain that she experienced in the days following her vaccination continued, separate and apart from any injury that she suffered as a result of her accident, and that said pain lasted for six months**.** Petitioner's argument is incomplete because it does not address the medical records' failure to indicate that Petitioner was experiencing shoulder pain after May 6, 2016 that was a continuation of the pain she experienced post vaccination. The witness declarations, however, taken together, demonstrate that Petitioner experienced shoulder pain within a week after her vaccination. L.W.1 stated that Petitioner's pain continued for about six to seven months, Pet'r's Ex. 11 ¶ 6, but L.W.1 did not explain when or how frequently Petitioner mentioned shoulder pain to her during that six- to seven-month period. L.W.2 mentioned that Petitioner complained about shoulder pain "for some time" but did not indicate if this was continuous or included complaints from the weeks or days preceding Petitioner's MVA. *See* Pet'r's Ex. 12 ¶ 8. D.C. stated that Petitioner's pain "continued for several months []" and noted that Petitioner had problems lifting her arm and sleeping on said arm. Pet'r's Ex. 23 ¶ 7. D.C. did not clarify whether he meant that Petitioner's complaints were consistent and present over "several months." The witness declarations were specific and clear enough on this point to establish by preponderant evidence that Petitioner experienced shoulder pain for at least six months. I find that Petitioner has presented preponderant evidence that she suffered from shoulder pain following her vaccination through October 2016. Whether this shoulder pain was caused by her vaccination will be analyzed below.

B. Table Injury

A determination of whether Petitioner suffered a Table injury requires factual determinations of (1) whether Petitioner experienced prior pain in the shoulder at issue, (2) whether the onset of her pain occurred within forty-eight hours of her vaccination, (3) whether her pain was limited to the shoulder at issue, and (4) whether Petitioner had any other conditions or abnormalities that could have caused her purported injury. Such determinations necessitate weighing the evidence presented. I conclude that Petitioner has fulfilled the first Table criterion

but has failed to satisfy the second, third, and fourth. Thus, Petitioner has not established that she suffered a Table injury.

1. Table Criterion One – Prior Shoulder Pain

Petitioner has satisfied the first criterion. Although Petitioner has had various medical conditions, including, for instance, prior leg and back pain, the record does not contain any indication that she had a history of pain or another ailment, or treatment for any such pain or ailment, in her right shoulder. By Petitioner's own admission, her mental illness has made it difficult to establish consistent care and establish relationships with providers. However, Petitioner's records are nonetheless extensive and demonstrate that Petitioner sought medical treatment when experiencing troubling symptoms. Further, Respondent has not disputed Petitioner's fulfillment of this criterion. I find that that the fact that the record does not reference prior shoulder pain is sufficient to establish the first criterion.

2. Table Criterion Two– Onset Within Forty-Eight Hours of Vaccination

The parties strongly disagree on the question of onset. Although Petitioner argues that her shoulder pain immediately followed the vaccination, Respondent argues that the onset, as indicated by the available medical records, was months after Petitioner's vaccination. There is testimonial evidence to support a conclusion that Petitioner's pain began within a week after her vaccination. However, this evidence is comprised of multiple witness statements that are inconsistent on exactly when Petitioner's pain began in the week following her vaccination. It is therefore insufficient to establish by a preponderant standard that her pain began within the forty-eight-hour window necessary to establish a Table claim. I have reached this conclusion after carefully weighing all of the medical records and the witness declarations.[23]

In Program cases, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Hum. Servs.*, 933 F.2d 1525, 1528 (Fed. Cir. 1993). "Medical records that are created contemporaneously with the events they describe are presumed to be accurate." *Robi v. Sec'y of Health & Hum. Servs.*, 2014 WL 167716, at *1 (Fed. Cl. Spec. Mstr. Apr. 4, 2014) (citing *Cucuras*, 993 F.2d at 1528). Medical records are "also presumed to be complete, in the sense that the medical records present all the problems of the patient." *Id.* Moreover, in Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). While a special master must consider the presented medical opinions and records, they are not "binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). Rather, when

[23] While the undersigned has reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

"evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

Judges of the Court of Federal Claims have reaffirmed the finding in *Cucuras* that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. *See, e.g., Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (Fed. Cl. 2010) ("Given the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law."), *aff'd sub nom. Rickett v. Sec'y of Health & Hum. Servs.*, 468 Fed. Appx. 952 (Fed. Cir. 2011) (nonprecedential opinion); *Doe/17 v. Sec'y of Health & Hum. Servs.*, 84 Fed. Cl. 691, 711 (2008); *Ryman v. Sec'y of Health & Hum. Servs.*, 65 Fed. Cl. 35, 41-42 (2005); *Snyder v. Sec'y of Health & Hum. Servs.*, 36 Fed. Cl. 461, 465 (1996) ("The special master apparently reasoned that, if Petitioner suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated Petitioner during his life to date. Finding Petitioner's medical history silent on his loss of developmental milestones, the special master questioned petitioner's memory of the events, not her sincerity."), *aff'd*, 117 F.3d 545, 547–48 (Fed. Cir. 1997).

The presumption that contemporaneously created medical records are accurate and complete is rebuttable. Special masters may determine that onset occurred on a certain date or within a certain timeframe despite a lack of confirmatory evidence in a contemporaneous medical record. 42 U.S.C. § 300aa-13(b)(2). However, "[p]ersuasive evidence is required to overcome the weight of medical records prepared for the purposes of diagnosis and treatment." *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). In particular, if the external evidence consists of eyewitness testimony from people with an interest in the case's outcome, said testimony must be "consistent, clear, cogent, and compelling." *Id.* When there is evidence that medical records may be incomplete, special masters are expected to consider the probative value of said evidence to determine whether the medical records are accurate and complete.

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

When weighing divergent pieces of evidence, special masters usually find contemporaneously written medical records to be more significant than oral testimony. *Cucuras*, 993 F.2d at 1528. Testimony offered after the events in question is less reliable than contemporaneous reports when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993). However,

compelling oral testimony may be more persuasive than written records. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (stating that this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate."); *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.") (citation omitted), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992).

Petitioner was unable to obtain records that are determinative of when her symptoms began, and the available records are unable to clarify onset. Petitioner claims that she visited Dr. Olasimbo to report her shoulder pain shortly after her March 23, 2016 vaccination, and that Dr. Olasimbo prescribed her Naproxen for her pain. Pet'r's Ex. 1 ¶ 7. While Petitioner recalled being prescribed Naproxen at an urgent care facility following her vaccination during her June 22, 2016 medical visit, Petitioner's pharmacy records do not substantiate this occurrence. Petitioner's pharmacy records show that she filled a Naproxen prescription on January 25, 2016. Pet'r's Ex. 21 at 5. They also demonstrate that she filled a Naproxen prescription on June 11, 2016. Pet'r's Ex. 22 at 2. These are the only two prescriptions for Naproxen noted in the pharmacy records. The pharmacy records do not provide support for her claim that she immediately sought care and received treatment. Ultimately, I cannot consider records from the urgent care facility because they are unavailable. The absence of evidence and/or a silent record is not necessarily a fatal flaw for a petitioner's claim. However, the available evidence in this case does not provide support for the possibility that Petitioner would have filled a Naproxen prescription received in March 2016 through another pharmacy.

The first reference to Petitioner's shoulder pain in the medical records is from May 28, 2016. However, Petitioner had seven medical or chiropractic visits between her March 23, 2016 vaccination and her May 28, 2016 medical visit. Petitioner complained of various symptoms and concerns, including abdominal cramping, diarrhea, vomiting, fatigue, a piece of wire coming out of her navel,[24] a cough, and potential mold exposure, on March 28, April 10, April 27, and May 23, 2016, but did not mention that she was experiencing shoulder pain. On May 11, 2016, Petitioner began treatment with Chiropractor Alfano. Although Petitioner's chiropractic records demonstrate that Chiropractor Alfano physically examined Petitioner and spoke with Petitioner about other ailments she was experiencing at the time, Petitioner's chiropractic records, from both before and after May 28, 2016, do not mention shoulder pain or injury. *See generally* Pet'r's Ex. 14.

[24] Petitioner's mental health has previously interfered with her ability to communicate symptoms with medical providers. On April 10, 2016, not long after Petitioner's vaccination, Petitioner presented to the ER with abdominal pain and complaining of a wire coming out of her navel. Pet'r's Ex. 4 at 10–11. However, the attending nurse was not able to see the "open sore" that Petitioner referred to. *Id.* at 15. Although this incident raises questions about Petitioner's credibility, there is evidence from Petitioner's CAT scan that at least some abnormality was present. *See id.* at 24. Further, this appeared to be an isolated incident. Due to differences in the circumstances, I still treat the witness declarations, when viewed together, as credible for the purpose of determining that Petitioner experienced symptoms within a week after her vaccination.

During her May 28, 2016 medical visit, Petitioner reported that she had been experiencing right upper arm and shoulder pain for more than two months. Pet'r's Ex. 4 at 5. However, that she did not discuss said pain during any of her medical visits in those two months with providers contradicts this assertion. Of the four types of explanations that the Court of Federal Claims has identified as explanations for inconsistencies between testimony and medical records, the two relevant here are the failure to recount symptoms and faulty recollection. Petitioner implies that she did not recount her shoulder symptoms to some providers. She stated in her second declaration that she saw Chiropractor Alfano specifically for treatment for injuries stemming from her MVA, not from her vaccination. Pet'r's Ex. 15 ¶¶ 8–12. Petitioner also asserts that she does not have a regular primary care doctor and "goes to various urgent cares and emergency rooms for her treatment as needed." Pet'r's Br. at 7. Despite Petitioner's explanations for the medical records' silence regarding her shoulder pain before May 28, 2016, as discussed in more detail below, her explanations are less credible due to inconsistencies in the record.

Petitioner's failure to mention her shoulder pain to Chiropractor Alfano is particularly troubling because Petitioner identified her chiropractor as someone who could alleviate her shoulder pain. Furthermore, the record demonstrates that Chiropractor Alfano should have noticed Petitioner's shoulder pain. Following a referral during her May 28, 2016 visit, Petitioner presented to an orthopedist regarding shoulder pain on June 6, 2016. Pet'r's Ex. 4 at 6; Pet'r's Ex. 17 at 5. The orthopedist, Dr. Henderson, noted that Petitioner "said that chiropractor in La Plata can cure this, and she will see him." Pet'r's Ex. 17 at 5. Yet, Petitioner had an appointment with Chiropractor Alfano that same day, June 6, 2016, and did not mention her shoulder pain. *See* Pet'r's Ex. 14 at 15–16. She also did not mention her shoulder pain during her June 14, 2016 or June 21, 2016 chiropractic appointments. *See id.* at 17–19. These omissions are especially notable considering that following the completion of Petitioner's chiropractic treatment, Chiropractor Alfano wrote in a June 23, 2016 note that "[a]s of this re-examination, [Petitioner] reported that since her previous exam, she had no new injuries, accidents, or illnesses that could have aggravated her original complaints *or caused any new complaints*." *Id.* at 20 (emphasis added). This disparity is further compounded by the fact that Dr. Henderson noted that Petitioner was wearing the sling she had obtained from the emergency room on May 28, 2016, during their June 6, 2016 visit. Pet'r's Ex. 17 at 5. Yet, Chiropractor Alfano's records from June 6, 2016, or any other date do not mention that Petitioner ever wore a sling. *See generally* Pet'r's Ex. 14. Chiropractor Alfano should have either seen the sling or determined through an examination or conversation that she had been wearing one or was experiencing arm pain. These inconsistencies detract from Petitioner's purported immediate onset.

Petitioner's medical records include her June 22, 2016 statement to a medical provider regarding her shoulder pain. Dr. Norwood noted Petitioner's complaints that the Naproxen she had purportedly been taking since visiting the urgent care facility post vaccination was not adequately controlling Petitioner's pain. Pet'r's Ex. 5 at 4. This record suggests that Petitioner continued to experience pain significant enough for prescription medication from March through June 2016. However, Petitioner's failure to recount her shoulder pain to her various providers flies in the face of this suggestion. Overall, Petitioner's medical records do not support that her symptoms began within forty-eight hours.

Because Petitioner's statements regarding onset are inconsistent, they do not persuasively fill in the gaps from the medical record and clarify the onset of her shoulder pain. In her declaration, Petitioner recalled telling Dr. Olasimbo that her "instantaneous and severe" pain began during the vaccination. Pet'r's Ex. 1 ¶ 7. However, when she filled out a physical therapy intake form on October 20, 2016, Petitioner stated that her symptoms emerged "[two] days after" the vaccination. Pet'r's Ex. 8 at 14. Additionally complicating reliance on Petitioner's non-contemporaneous statements, Petitioner's medical history includes a disorder that has the potential to interfere with the content of thought.[25] She also has reported problems with her memory to healthcare providers. *See* Pet'r's Ex. 18 at 18.

Although Petitioner's witness declarations were presented to support Petitioner's claim that the onset was within forty-eight hours, they do not do so. However, they do provide some support that the onset of Petitioner's pain was before when Respondent asserts and when the medical records reflect. The declarations do not provide information sufficient to overcome Petitioner's medical records and recollections.

Petitioner's witness declarations substantiate that Petitioner complained of shoulder pain within days of her vaccination. All four witnesses, while personally connected to Petitioner, recall Petitioner complaining about shoulder pain within approximately one week post vaccination. Petitioner's friend, T.T., reported that she first heard Petitioner complain about her shoulder injury during what T.T. believed to be the weekend after Petitioner's birthday. Pet'r's Ex. 22 ¶ 7. If T.T. is correct, this would have been within three to five days after Petitioner's vaccination. Petitioner's daughter, L.W.1, reported that Petitioner experienced pain in her left, rather than right, shoulder. Pet'r's Ex. 11 ¶ 5. This, however, may be an error rather than an inconsistency. Although L.W.1 did not clarify how often she spoke to Petitioner at the time of Petitioner's vaccination, she stated in her declaration, signed on April 18, 2018, that she spoke to Petitioner "almost every other day on the telephone." *Id.* ¶ 7. L.W.1 stated that Petitioner's "pain began immediately after the vaccination[,]" but she did not specify when Petitioner reported this to her, other than that it was "within a few days after" Petitioner's vaccination. *Id.* ¶ 5.

Petitioner's daughter, L.W.2, stated in her April 18, 2018 declaration, that she "speak[s] to [Petitioner] about five to six (5-6) times per day." Pet'r's Ex. 12 ¶ 10. L.W.2 reported that Petitioner complained about post-vaccination shoulder pain during a phone call that occurred about a week after Petitioner's vaccination, but L.W.2 did not otherwise provide information about the onset of Petitioner's injury. *Id.* ¶ 6. L.W.2 also recalled observing Petitioner having trouble lifting her arm. *Id.* ¶ 7. Petitioner's husband, D.C., recalled Petitioner complaining of arm pain the day after her vaccination. Pet'r's Ex. 23 ¶ 6. None of Petitioner's witnesses besides her husband, who prepared his declaration more than three years after Petitioner's vaccination, reported hearing of Petitioner's pain within forty-eight hours of vaccination.

Taken together, the statements of Petitioner's witnesses support her contention that she began experiencing shoulder pain within the week after her vaccination. Therefore, I conclude by a preponderant standard that Petitioner experienced shoulder pain within one week after her vaccination. The witness statements still, however, present small inconsistencies in timing. These statements also cannot be reconciled with Petitioner's medical records.

[25] *See supra* note 3 and accompanying text.

The declarations and overall record, therefore, contain insufficient evidence to support an affirmative finding that Petitioner experienced shoulder pain within forty-eight hours after her vaccination. Only one of Petitioner's witnesses, L.W.1, stated that Petitioner's pain began immediately after her vaccination. L.W.1 also stated, however, that she did not hear about the pain until "within a few days after" the vaccination. It is notable, given how regularly Petitioner's daughters reported they speak to Petitioner, that Petitioner's husband was the only witness who recalled discussing Petitioner's pain with her within forty-eight hours of her vaccination. Although the declarations mitigate the lack of mention of shoulder pain in contemporaneous medical records to an extent, they are not clear and consistent enough to overcome the medical records for the purpose of the second criterion. The declarations fail to substantiate, by a preponderant standard, that Petitioner's onset was within forty-eight hours. Therefore, I do not find sufficient evidence to conclude by a preponderance of the evidence that Petitioner has fulfilled the second Table criterion.

3. Table Criterion Three– Pain Limited to the Affected Shoulder

There is no indication in the record that Petitioner reported to her family members that she was experiencing pain in any other area of her body when she complained to them of shoulder pain within a week after her vaccination. However, the evidence in the record is insufficient to establish by a preponderant standard that this initial pain is the only shoulder pain Petitioner suffered during the timeframe applicable to an actionable vaccine injury. As noted above, in order for Petitioner to meet the threshold for Program compensable injury, she must establish her vaccine injury lasted six months. During the applicable six-month period in this case, Petitioner experienced pain in other places besides her right shoulder as early as May 6, 2016. Petitioner provided evidence by way of declarations to support an initial finding that Petitioner's pain was limited to her shoulder. However, Petitioner's medical records contain evidence that the pain Petitioner experienced within a week after her vaccination resolved. As discussed above, Petitioner did not mention her shoulder pain to Chiropractor Alfano during her May and June 2016 chiropractic appointments even though she identified her chiropractor as the appropriate person to treat her shoulder pain. *See* Pet'r's Ex. 17 at 5. Petitioner's medical records indicate that when she actively sought medical treatment for pain that she ultimately alleged resulted from her vaccination, Petitioner was suffering from pain in other areas, including in the vicinity of her right shoulder. In fact, Petitioner's medical records suggest that she did not seek any treatment for shoulder pain until after she was involved in her MVA and had attributed her other injuries to that incident. In light of the entire record, I conclude that it is more likely than not that during the relevant six-month period, that Petitioner experienced pain in other areas of her body beginning on May 6, 2016. Therefore, by a preponderant standard, Petitioner has not fulfilled the third criterion.

4. Table Criterion Four – Alternative Cause of Shoulder Pain

Petitioner's claim does not fulfill the fourth criterion because her May 6, 2016 MVA amounts to a potential alternative cause of some of the shoulder pain Petitioner experienced within the requisite six-month period. The record does not evidence any cause besides the March 23, 2016 vaccination for Petitioner's shoulder pain that she described to family members in the days following her vaccination. Petitioner contends that the shoulder pain she reported to providers after

May 6, 2016 also stemmed from her vaccination. However, the record is not as clear on that point, and her MVA cannot be ruled out as a potential alternative cause. Thus, I cannot conclude, by a preponderant standard, that Petitioner meets the fourth criterion.

C. Causation-in-fact

Petitioner was unable to satisfy all of the factors necessary to pursue her claim as a Table injury. Because Petitioner has not established that she suffered a Table injury, I now review her alternative claim that her shoulder injury was caused-in-fact by her Hepatitis B vaccination. I conclude that Petitioner has not proffered sufficient evidence to establish by a preponderance of the evidence that the vaccination was the cause-in-fact of her injury. Petitioner has fulfilled the first prong of *Althen* but not the second or third prong.

1. *Althen* Prong One

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548; *see also Andreu v. Sec'y of Health & Hum. Servs.*, 569 F. 3d 1367, 1375, 1379 (2009) (ruling that the petitioners had satisfied *Althen* prong one where their expert witness had "presented a 'biologically plausible' theory"). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548–49. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

The Vaccine Injury Table identifies SIRVA as an injury that, under certain circumstances, may be presumed to be caused by a Hepatitis B vaccination. Judges in the Court of Federal Claims have acknowledged that such a link to a Table injury can support a petitioner's ability to fulfill *Althen*'s first prong. *See Doe 21 v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 178, 199 (2009), *rev'd on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013) (determining that a petitioner fulfilled *Althen* prong one, in part, because "the Table recognizes that a vaccine containing pertussis can cause encephalopathy[]"). Additionally, the Court of Federal Claims indicated that "a medical theory causally connecting" a given vaccine and a given injury that has been "well recognized by the Office of Special Masters[]" can support a petitioner's fulfillment of the first prong. *See id.* Special masters have previously taken judicial notice of the fact the Table links SIRVA to certain vaccines and have additionally noted that "there is a well-established track record of awards of compensation for SIRVA being made on a cause-in-fact basis in this program." *See, e.g.*, *Porcello v. Sec'y of Health & Hum. Servs.*, No. 17-1255V, 2020 WL 4725507, at *6–7 (Fed. Cl. Special Master June 22, 2020). Medical literature, epidemiological studies, and/or demonstrations of specific mechanisms are not necessarily required for a petitioner to present a sufficient medical theory. *Id.*, at *6 (citing *Andreu*, 569 F.3d at 1378–1379).

Petitioner argues that she satisfies the first prong because she experienced "immediate" shoulder pain upon receipt of the vaccine. Pet'r's Br. at 14–15. She asserts that "[i]mproper administration of a vaccination is a medical theory that connects the vaccination and injury. *Id.* at 15. This is simply the medical theory underlying Table SIRVA. Thus, Petitioner has put forth a biological mechanism, pursuant to the Table, of her injury. Because she has alleged that onset occurred immediately, Petitioner has put forth an acknowledged biological mechanism that pertains to her case. I conclude that Petitioner has fulfilled *Althen*'s first prong.

2. *Althen* Prong Two

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1380; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The Court in *Pafford* noted petitioners "must prove [] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface*, 165 F.3d at 1352). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325–26.

When considering whether a petitioner has fulfilled this prong, special masters determine whether the record shows, by a preponderance of the evidence, that a petitioner's injury was actually caused by the vaccine in question. "There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine." *Capizzano*, 440 F.3d at 1327. A special master may deny that a petitioner has fulfilled the second prong "when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving the vaccine caused the injury by a preponderance of the evidence." *Id.*

Petitioner has not satisfied the second prong because she has not provided a "sequence of cause and effect" that is logical in light of her proffered theory. As discussed above, Petitioner's medical theory amounts to a restatement of a Table SIRVA's medical theory. Yet, that theory, as reflected in the Table, requires that SIRVA symptoms manifest forty-eight hours or less after vaccination. *See* 42 C.F.R. § 100.3(a)(XIV). Petitioner alleges that she experienced shoulder pain within that time-frame. However, I have already determined that the record contains insufficient evidence to support such a finding by a preponderant standard. Thus, Petitioner has not connected her purported theory with her injury.

Petitioner has not proffered a logical sequence of cause and effect pursuant to her claimed medical theory. I conclude that Petitioner has not established *Althen*'s second prong by a preponderance of the evidence.

3. *Althen* Prong Three

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

Petitioner has not fulfilled the third prong. Petitioner's causal theory requires that she experienced symptoms within forty-eight hours after her vaccination. Petitioner has not presented any evidence of a medically appropriate timeframe other the Table. As previously stated, the record fails to support that Petitioner experienced symptoms within forty-eight hours. Thus, Petitioner has not established a proximate temporal relationship between her vaccination and injury.

VI. Conclusion

After a careful review of the record, Petitioner has failed to prove by preponderant evidence that she suffered a Table injury or, alternatively, that she suffered an injury that was caused-in-fact by her Hepatitis B vaccination. Accordingly, I have no choice but to **DENY** Petitioner's claim and **DISMISS** her petition.[26]

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

[26] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.